



APR - 4 2019

Administrator

Washington, DC 20201

The Honorable Doris Matsui
U. S. House of Representatives
Washington, DC 20515

Dear Representative Matsui:

Thank you for your letter to Secretary Azar regarding the proposed changes to the protected class policy as part of the Administration's efforts to lower prescription drug prices. The Secretary asked that I reply to your letter. The President and the Department of Health and Human Services are committed to putting American patients first by addressing the rising cost of prescription drugs for all Americans. We appreciate hearing your concerns on this important issue.

The Centers for Medicare & Medicaid Services' (CMS) proposed rule, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," was released on November 26, 2018. We are reviewing public comments in response to the proposal before issuing a final rule.

We believe our proposal would provide Medicare Part D drug plans with more tools to negotiate lower drug prices and provide seniors with more plan options featuring lower costs for prescription drugs. In particular, this policy proposal is intended to allow Part D sponsors to better manage protected class drugs and provide them with additional tools to negotiate as competitive a price as possible in order to provide drug pricing relief to Medicare Part D enrollees, while maintaining beneficiary access to protected class drugs when used for protected class indications.

CMS established the protected class policy primarily to ensure a smooth implementation when the Part D program was started in 2006. However, as the proposed rule describes, one unintended consequence of the protected class policy is that beneficiaries are not getting the best negotiated prices for many of these drugs that have competitors and instead are paying higher out of pocket costs for these drugs. As stated in the proposed rule, CMS has concluded that despite some formulary and utilization management flexibility, Part D sponsors are not able to negotiate rebates across the protected classes at levels commensurate with other Part D drugs or the commercial market.

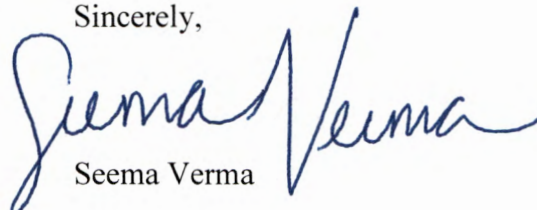
CMS has been deliberate in the development of the proposal that, if finalized as proposed, would continue to ensure timely access to needed medications. As contemplated in the proposed rule, the formularies approved by CMS would continue to include drugs that treat all the conditions in the protected classes, and CMS would continue to have several safeguards in place that we believe would ensure beneficiary access to needed drugs, should this proposal be finalized.

These safeguards include our current rigorous annual formulary review and approval process, which includes extensive checks to ensure appropriate representation of drugs for all necessary Part D drug categories or classes for beneficiaries, including looking at widely accepted treatment guidelines. The current formulary review process includes a review for any discriminatory practices. Further, as envisioned in the proposed rule, beneficiaries would be able to utilize the existing appeals and exceptions process to ensure access to necessary medications.

CMS's current formulary review process and protections ensure that enrollees who have been stabilized on an existing therapy would not have to change to a different drug in order to progress through step therapy requirements. We only approve prior authorization criteria that are clinically supported. We also conduct a discrimination review to ensure that plans' formulary designs are not likely to substantially discourage enrollment by certain Part D eligible individuals, in addition to the review of compliance with the two drugs per class requirement. CMS's Part D transition policy requires that sponsors provide all new enrollees that are currently taking a drug with a one-month fill if utilizing prior authorization or step therapy. This allows for an appropriate time for a beneficiary to file an appeal to continue necessary medications if they are already stabilized on another medication, for instance. As we indicated in the proposed rule, these beneficiary protections would continue to apply to protected class drugs.

Thank you again for bringing your concerns to our attention. We look forward to continuing to work with you and other stakeholders to help ensure the continued success of the Medicare Prescription Drug Benefit for Medicare beneficiaries and taxpayers. I will share a copy of this response with the co-signers of your letter.

Sincerely,

A handwritten signature in blue ink that reads "Seema Verma". The signature is fluid and cursive, with the first and last names being clearly legible.

Seema Verma